

Remarks

Claims 1-18 are in the case. Each of the claims stands rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. No. 6,468,284 to Wallace. The rejection is respectfully traversed.

As previously noted, each of Applicant's independent claims 1, 5 and 17 recite patentably distinct elements that are not taught or suggested by Wallace, and which serve to patentably distinguish the parties' respective teachings.

For example, each of independent claims 1, 5 and 17 recite at least the following patentably distinct claim elements:

Claim 1: "means for measuring electronically the magnitude of the extraction force applied to the fetal head during a vacuum extraction";

Claim 5: "means for measuring the extraction forces exerted on the fetal head, said means contained in said handle grip"; and

Claim 17: "means for measuring the extraction forces on the fetal head".

As seen, the common term between and amongst these clauses is a "means for measuring the extraction forces" applied to the head of the baby while extracting the child during delivery.

The Applicant's invention is therefore novel in that it addresses specifically, and for the first time, the issue of the fetal risks associated with cup detachment ("pop off"), caused by the inadvertent application of extraction greater than the negative-suction force of the cup adhered to a child's head during a vacuum-assisted delivery.

This invention was prompted by relatively recent scientific evidence, demonstrating unquestionably that cup "pop-offs" are not merely a threshold safety consideration as previously thought, but rather a major risk factor for serious fetal injury, thus making it desirable to provide

physicians with a means for avoiding them altogether (rather than just limiting their number) through close monitoring of the application of extraction force (See, for example, Towner D. Castro MA, Eby-Wilkens E., et al., *Effect of mode of delivery in nulliparous women on neonatal intracranial injury*, N Engl J Med 1999; 341:1709-1714).

In contrast, Wallace does not anticipate (or even contemplate) the issue of limiting the amount of traction during a vacuum-assisted delivery in order to avoid cup "pop-offs," as demonstrated by the fact that Wallace neither mentions nor implies in his patent that its objective is to measure the magnitude of the traction force. In fact, contrary to the pending rejection, in col. 3 lines 3-7 and 17-23, Wallace does not disclose a means to measure the magnitude of any traction forces, but instead merely the means to indicate whether traction is being applied or not, which is not surprising since Wallace is concerned only with the issue of whether and how many times traction is being applied during a vacuum-assisted delivery.

This is not a minor difference. While it is true that both applications disclose *strain gauges*, those of ordinary skill in the electronics engineering arts will readily appreciate that an indication of the "application of traction" (*i.e.*, whether traction is being applied or not), and the actual measurement of the magnitude of traction, are two different issues. From a technical standpoint, for example, an application of force measurement requires only the use of a *comparator*, being basically an "on or off" event, whereas the measure of the magnitude of traction requires an *analog to digital converter* (ADC).

Further evidence that the Applicant measures something totally different from Wallace's can be found in the transmission and recording of the data and in the alarm systems. For example, whereas in the present invention it is the magnitude of the traction force applied that is transmitted,

recorded and printed, in Wallace's patent what is recorded is the duration of vacuum application and vacuum magnitude (col.7 lines 17-19).

As for the alarm, whereas the Applicant's invention is configured to alert the doctor when the traction force approaches a level sufficient to cause the fetal cup to detach, in Wallace's patent the alarm is coupled to a timer and triggered when the vacuum application rises above a certain threshold magnitude" (q.v. at id: "... upon reaching a specific time or duration of vacuum application above a certain threshold magnitude").

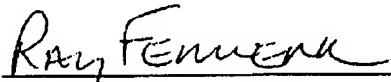
In short, the suction force of a cup against a baby's head is different from the traction force applied to a device that has been adhered to a baby's head. Even one of only nominal skill in the art, for example, can appreciate that two such devices applied to two different babies with the same suction force will generally require different traction forces to remove the baby, the difference in traction forces required being attributable to differences in the manner in which the child is disposed in the birth canal, the birthing characteristics of the mother, *etc.*

When one considers the major safety issues of vacuum-assisted delivery, it is easy to understand why the Applicant's invention is an improvement over Wallace's patent. In fact, while Wallace's patent addresses some of the risk factors associated with vacuum-assisted delivery, such as the magnitude of the vacuum, the duration of the vacuum application on the fetal head and the number of times traction is applied, it ignores entirely the more recently recognized risk of fetal injury associated with cup "pop-offs", resulting from excessive application of traction, and therefore fails to teach any methods or means of measuring traction forces. Even the nominal strain gauge contemplated by Wallace is present only as a comparator to detect the number of times traction is applied, *not* to measure the extracting traction forces applied to the child's head given the fixed, previously known negative suction force of the cup against the child's head.

Conclusion

In view of the foregoing, Applicant submits that all outstanding grounds of rejection have been overcome with respect to independent claims 1, 5 and 17, each of which should now be allowed. Since all remaining claims in the case depend either directly or indirectly from allowable claims 1, 5 and 17, it follows that all of the remaining claims are also necessarily allowable under the doctrine of *In re Fine*, q.v. at 5 USPQ2d 1596 (Fed. Cir. 1988). Reconsideration and withdrawal of the rejections, and allowance of all claims pending in the case at an early date, are respectfully requested.

Respectfully submitted,



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